

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

BARBET DENNIS,

Plaintiff,

v.

CIVIL ACTION NO. 2:16-cv-10815

C. R. BARD, INC.,

Defendant.

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: Ralph Zipper, M.D.)

Pending before the court is Defendant C.R. Bard, Inc.'s Motion to Exclude or Limit Certain Opinions and Testimony of Ralph Zipper, M.D. [ECF No. 27] filed by defendant C. R. Bard, Inc. ("Bard"). The plaintiff did not file a response. Thus, the Motion is ripe for adjudication.

I. BACKGROUND

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation ("MDL") concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 24,000 cases currently pending, approximately 3,000 of which are in the Bard MDL, MDL No. 2187.

In an effort to manage the massive Bard MDL efficiently and effectively, the court decided to conduct pretrial discovery and motions practice on an individualized basis. To this end, I ordered the plaintiffs and defendants to submit a joint list of

remaining cases in the Bard MDL, MDL 2187, with claims against Bard and other defendants where counsel has at least 20 cases in the Bard MDL. The list included nearly 3,000 cases. From these cases, I selected 332 cases to become part of a “wave” of cases to be prepared for trial and, if necessary, remanded. *See* Pretrial Order No. 244, *In re C. R. Bard, Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:10md-02187, March 3, 2017, <https://www.wvsc.uscourts.gov/MDL/2187/orders.html>. Upon the creation of a wave, a docket control order subjects each active case in the wave to the same scheduling deadlines, rules regarding motion practice, and limitations on discovery. I selected the instant civil action as a Wave 5 case.

II. LEGAL STANDARD

By now, the parties should be intimately familiar with Rule 702 of the Federal Rules of Evidence and *Daubert*, so the court will not linger for long on these standards.

Expert testimony is admissible if the expert is qualified and if his or her expert testimony is reliable and relevant. Fed. R. Evid. 702; *see also Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993). An expert may be qualified to offer expert testimony based on his or her “knowledge, skill, experience, training, or education.” Fed. R. Evid. 702. Reliability may turn on the consideration of several factors:

- (1) whether a theory or technique can be or has been tested;
- (2) whether it has been subjected to peer review and publication;
- (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and
- (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 592–94). But these factors are neither necessary to nor determinative of reliability in all cases; the inquiry is flexible and puts “principles and methodology” above conclusions and outcomes. *Daubert*, 509 U.S. at 595; *see also Kumho Tire Co. v. Carmichael*, 525 U.S. 137, 141, 150 (1999). Finally, and simply, relevance turns on whether the expert testimony relates to any issues in the case. *See, e.g., Daubert*, 509 U.S. at 591–92 (discussing relevance and helpfulness).

In the context of specific causation expert opinions, the Fourth Circuit has held that “a reliable differential diagnosis provides a valid foundation for an expert opinion.” *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 263 (4th Cir. 1999).

A reliable differential diagnosis typically, though not invariably, is performed after ‘physical examinations, the taking of medical histories, and the review of clinical tests, including laboratory tests,’ and generally is accomplished by determining the possible causes for the patient’s symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is the most likely.

Id. at 262 (citations omitted). “A differential diagnosis that fails to take serious account of other potential causes may be so lacking that it cannot provide a reliable basis for an opinion on causation.” *Id.* at 265. However, an expert’s causation opinions will not be excluded “because he or she has failed to rule out every possible alternative cause of a plaintiff’s illness.” *Id.* “The alternative causes suggested by a defendant ‘affect the weight that the jury should give the expert’s testimony and not the admissibility of that testimony,’ unless the expert can offer ‘no explanation for why

she has concluded [an alternative cause offered by the opposing party] was not the sole cause.” *Id.* at 265 (citations omitted).

At bottom, the court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper*, 259 F.3d at 200.

III. DISCUSSION

A. General Causation

First, Bard challenges Dr. Zipper’s opinions on product design and the purported characteristics of the polypropylene. However, that topic is the province of a general causation expert—not a specific causation expert. In PTO No. 244, I directed the parties to file general causation objections in the main MDL. I will not rule on general causation issues raised in a specific causation motion. Accordingly, C.R. Bard’s Motion on this point is **DENIED**.

Second, Bard argues that I should exclude Dr. Zipper’s specific causation testimony because it is insufficiently grounded in general causation testimony. However, after reviewing the record, I determine that Dr. Zipper’s specific causation opinion is sufficiently grounded to move forward. To the extent Bard believes Dr. Zipper’s opinions are lacking, Bard may attack those opinions on cross-examination. Bard’s Motion on this point is **DENIED**.

However, because specific causation experts are tasked with connecting the individual plaintiff’s injuries to the allegedly defective product, Dr. Zipper may not offer broad testimony regarding the sorts of harms pelvic mesh can allegedly cause. Rather, Dr. Zipper’s testimony must focus on the harms the pelvic mesh allegedly

caused in this particular plaintiff. To the extent that Bard's Motion raises this point, the Motion is **GRANTED**.

Lastly, Bard challenges the admissibility of Dr. Zipper's opinions and conclusions regarding Bard's compliance with FDA regulations. As previously stated, assuming that such testimony would be admissible, this would be a topic reserved for a general causation expert only. Therefore, Bard's Motion on this point is **DENIED**. Notably, this Court has addressed this issue *ad nauseam* in a multitude of previous orders, and has not and will not allow a proposed expert to opine on a manufacturer's compliance with FDA regulations.

B. Differential Diagnosis

Bard argues that Dr. Zipper failed to perform a reliable differential diagnosis. I disagree. Dr. Zipper is an urogynecologist who is board certified in female pelvic medicine and reconstruction. He has performed thousands of transvaginal mesh procedures for the treatment of pelvic organ prolapse and incontinence, including native tissue repairs, allograft repairs, xenograft repairs and synthetic mesh repairs. Def.'s Mot. to Exclude Ops. of Ralph Zipper, M.D., Ex. A (Zipper Expert Report), at 2-4 [ECF No. 27-1]. He also has experience implanting and explanting multiple constructions of polypropylene mesh. *Id.* Dr. Zipper's expert report and deposition testimony show that he conducted a detailed review of the plaintiff's medical records. Though he did not perform a physical examination of the plaintiff, Dr. Zipper considered numerous alternative causes for the plaintiff's injuries and concluded that they could be ruled out as a cause of the plaintiff's injuries. In his deposition, Dr.

Zipper explained in more detail his reasons for ruling out these various alternative causes. *See* Def.’s Mot. to Exclude Ops. of Ralph Zipper M.D., Ex. B (Zipper Dep.), at 135:23 –139:19 [ECF No. 27-2].

As discussed above, an expert’s causation opinions will not be excluded “because he or she has failed to rule out every possible alternative cause of a plaintiff’s illness.” *Westberry*, 178 F.3d. at 265. Bard’s suggested other possible alternative causes affect the weight—not the admissibility—of an expert’s testimony, unless the expert can provide *no* explanation for ruling out such alternative causes at trial. *See id.* at 265. To the extent that Bard believes that Dr. Zipper failed to consider other alternative causes properly or varied his confidence in his assessments, Bard is free to address those issues on cross-examination. Bard’s Motion on this point is **DENIED**.

IV. METHODOLOGY

Bard next argues that I should exclude Dr. Zipper’s opinions because his opinions are based on unreliable methodology. However, after reviewing the record, I determine that the challenged opinion is sufficiently reliable to move forward. To the extent Bard believes the challenged opinion is deficient, Bard may attack that opinion on cross-examination. Bard’s Motion on this point is **DENIED**.

V. STATE OF MIND

Bard argues that I should preclude Dr. Zipper from testifying as to Bard’s state of mind. I agree; experts may not testify about that other parties did or did not know. However, to the extent that Bard seeks to exclude Dr. Zipper’s testimony about factual issues or the knowledge of the medical community in general, I disagree.

Expert witnesses may properly offer opinions on these topics. Bard's Motion is **GRANTED** to the extent it seeks to exclude evidence regarding Bard's state of mind.

VI. FUTURE ADVERSE EVENTS

Bard next argues that I should exclude Dr. Zipper's testimony regarding potential future complications because that testimony is speculative and unreliable. However, after reviewing the record, I determine that the challenged testimony is sufficiently grounded to move forward. To the extent Bard believes that the challenged opinion is deficient, Bard may attack it on cross-examination. Bard's Motion on this point is **DENIED**, and any remaining issues are **RESERVED** for trial.

VII. CONCLUSION

The court **ORDERS** that the Defendant C.R. Bard, Inc.'s Motion to Exclude or Limit Certain Opinions and Testimony of Dr. Ralph Zipper M.D. [ECF No. 27] is **DENIED in part. GRANTED in part** and **RESERVED in part**. The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: February 1, 2018



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE